



DEC 21 2005

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Re: Patent Term Extension
Application for
U.S. Patent No. 5,385,732

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,385,732, which claims the human biological product, TNKase™ (tenecteplase), and a method of its use, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 853 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 853 days.

The period of extension, if calculated using the Food and Drug Administration's (FDA) determination of the length of the regulatory review period would be 1,100 days. FDA's determination was published in the Federal Register of September 27, 2001 (66 Fed. Reg. 49392). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1741 - 40) + 249 \\ &= 1,100 \text{ days}\end{aligned}$$

Since the regulatory review period began December 23, 1994, before the patent issued (January 31, 1995), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From December 23, 1994 to and including January 31, 1995 is 40 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period: $1741 - 40 = 1701$ days.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,100 days, would extend the patent from January 31, 1995 (35 U.S.C. § 154) to February 3, 2015, which is beyond the 14-year limit (the approval date is June 2, 2000, thus the 14 year limit is June 2, 2014). The period of extension is thus limited to 853 days, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, January 31, 2012, to and including June 2, 2014.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

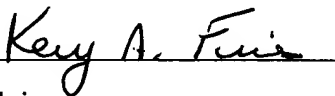
Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,385,732
Granted:	January 31, 1995
Original Expiration Date:	January 31, 2012
Applicant:	Stephen Anderson, et al.
Owner of Record:	Genentech, Inc.
Title:	VARIANTS OF TISSUE PLASMINOGEN ACTIVATOR, COMPOSITIONS AND METHODS OF USE FOR SAME
Product Trade Name:	TNKase™ (tenecteplase)
Term Extended:	853 days
Expiration Date of Extension:	June 2, 2014

Any correspondence with respect to this matter should be addressed as follows:

By mail:	Commissioner for Patents	By FAX:	(571) 273-0100
	Box Patent Ext.	Attn:	Mary C. Till
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Telephone inquiries related to this determination should be directed to Mary C. Till at (571) 272-7755.


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FDA Docket No.: 01E-0098
RE: TNKase™ (tenecteplase)